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APPLICATION NUMBER: NDA 20089/S2

CORRESPONDENCE

Dr
2/19/92

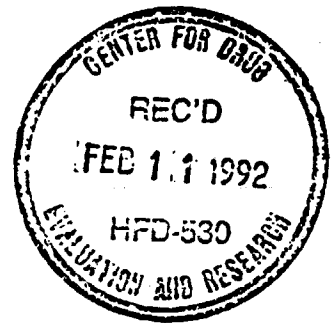


Burroughs Wellcome Co.

Donald A. Knight
Vice President
Drug Regulatory Affairs and
Scientific Administration

CR16

NDA NO. 20-089 REF. NO. 332
NDA SUPPL FOR SEI DRAFT



February 11, 1992

SEI 002

David W. Feigal, Jr., M.D., Director
Division of Antiviral Drug Products, HFD-530
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: SUPPLEMENTAL NEW DRUG APPLICATION
NDA 20-089
ZOVIRAX® (Acyclovir) Tablets

Dear Dr. Feigal:

We are submitting herewith a Supplemental New Drug Application to provide for the use of ZOVIRAX Tablets in the treatment of primary varicella infections.

For safety and efficacy data in support of this supplemental application, reference is made to our supplemental NDA for ZOVIRAX Suspension (NDA 19-909/S-003) submitted October 18, 1990.

A copy of the proposed package insert, identical to that submitted on this date to the ZOVIRAX Capsules and Suspension Supplemental NDAs, is attached. This package insert reflects changes discussed in the February 4, 1992, discussions between members of your division and B.W. Co.

If you have any questions concerning this application, please contact Dr. Beverly Atwood at (919) 248-8076.

Sincerely,

Donald A. Knight

TRZO/92/0073
DAK/cp(pr)*
Enclosure